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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/734,008	12/12/2000	Uwe Heinelt	02481.1718	3747

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EXAMINER

SACKEY, EBENEZER O

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 06/27/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/734,008

Applicant

HEINELT ET AL.

Examiner

EBENEZER SACKKEY

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 3, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 20, 21, 23-30, 32-34, and 38-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-16, 18, 19, 22, 31, 35-37, and 48-50 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Claims 1-50 are pending.

This is a response to applicants amendment A, filed on 4/03/02. Applicants amended claim 1 by replacing "derivative" to --compound--. It is suggested that the expression "results", page 2, line 2, under the definition of So be replaced with --is obtained--. Additionally, --salt-- be inserted after "trifluoroacetate"; page 1, lines 3 and 5 respectively; --of-- be inserted on line 1 of claims 7 and 16, after compound.

Claim Rejections - 35 U.S.C. § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 17, 20-21, 23-30, 32-34 and 38-47 are rejected under 35

U.S.C. 112, first paragraph, as containing subject matter which was not

described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are drawn to methods of using compounds of formula (I) or (Ia) in treating or preventing various disease states. See page 13. It is noted that the specification provides disclosures for diuresis experiment, page 49, which is drawn to a specific activity.

It is noted that the specification provides disclosures for biological assays for diuresis (pharmacological data page 49, and Table on page 50) which are drawn to specific activities. The claims as recited would give rise to undue experimentation to one of ordinary skill to ascertain how those diseases are treated or prevented. It is noted that one of ordinary skill in the art would not extrapolate the broad spectrum of applicability asserted in the instant methods (i.e., the treatment or prevention of the diseases listed) from the limited examples and disclosure of the instant application.

For rejections under 35 U.S.C. 112, first paragraph, certain factors must be considered under the holding in *In re Wands*, 8 U.S.P.Q. 2d 1400, 1404 (CAFC, 1988):1) the nature of the invention is that of using the

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compounds of formula (I) or formula (Ia) in treating various diseases listed; 2) substituted norbornylamino compounds are known in the art; 3) the level of predictability is low, as is true of most biological and chemical systems; 4) the amount of guidance provided by the inventors is minimal since no disclosure is provided for the treatment or prevention of the diseases listed; no teaching as to how these activities correlate to the various diseases. The instant specification provides no direction for performing methods commensurate in scope with the instant claims; 5) the existence of working examples is limited to the preparation of the compounds as note Examples 1-16 etc.; 6) therefore, an undue quantity of experimentation would be needed to make the invention based on the content of the disclosure. At best, the method currently asserted for broadly treating the various disease state would be more adequately described as a method for treating hypertension. "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with

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respect to the direction in which the experiment should proceed.” *In re Wands*, 8 U.S.P.Q. 2d 1400, 1404 (CAFC, 1988).

The disclosure is devoid of disclosures which would direct the skilled artisan in methods for treating all the diseases listed on page 13. It is suggested that “prevention” be deleted from the claims. Such would appear to put the claims in condition for allowance.

Schwark et al. U.S. Patent number 6,005,010 is cited to show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (703) 305-6889. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (703) 308-4537. The fax phone number for this Group is (703) 308-4556.

DEBORAH C. LAMBIN
PRIMARY EXAMINER

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

EOS


DEBORAH C. LAMBKIN
PRIMARY EXAMINER

June 25, 2002

Joseph K. McKane

Supervisory Patent Examiner

Art Unit 1626, Group 1600

Technology Center 1